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Los Alamos NATIONAL LABORATORY EST.1943

# Environmental Stewardship– Environmental Characterization and Remediation

## Quality Procedure

# for Corrective Action Process

☑ **NES Approved**

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| Responsible Division Leader:<br>Doug Stavert | Signature & Date<br>for Doug Stavert 3/9/06 |
| Responsible Line Manager:<br>Alison Dorries | Signature & Date<br>3/9/06 |

## Revision Log

| Revision No. | Effective Date | Prepared By | Description of Changes | Affected Pages |
|---|---|---|---|---|
| R0 | 05/19/98 | Andrew E. Gallegos | New procedure | All |
| R1 | 07/01/98 | Andrew E. Gallegos | Editorial changes | All |
| R2 | 08/31/01 | Andrew E. Gallegos | Complete rewrite to replace QP-3.4, Revision 1, Reporting and Correcting Nonconformances | All |
| R3 | 07/01/2004 | Andrew E. Gallegos | Revised to address PAAA requirements, suspect/counterfeit items, QP title and logo change, new Attachment B, and new QP format | All |
| R3, ICN1 | 4/8/2005 | Andrew E. Gallegos | Modified the CAR form to enable the user to enter information appropriately; revised Section III to read ENV-RS PAAA and changed the footer to read ENV-ECR | Attachment B |
| R3, ICN2 | 10/17/05 | J. Kolakowski | Changed Sections 6.8 and 6.9 to clarify CAR revision process and trend report; added Rev.# space to CAR report | 15, and Attachment B (p. 2 of ICN1) |
| R4 | 3/10/06 | J. Kolakowski | Made organizational changes, updated definitions, added Section 6.1.8 re: causal analysis, updated PAAA determination section, changed procedure for revising or modifying CARs, added trend report | 5–8, 9–10, and 12 |
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# QP-3.4, Corrective Action Process, R4

## Table of Contents

# QP-3.4, Corrective Action Process, R4

## 1.0 PURPOSE

This quality procedure (QP) states the responsibilities and describes the process for providing a consistent mechanism for identifying, logging, resolving, and reporting conditions adverse to quality. The data captured in this system allow management to make informed decisions about how to employ resources efficiently to solve systemic problems. The success of this process ties directly to the participation of each employee within the Los Alamos National Laboratory (LANL or the Laboratory) Environmental Stewardship Division (ENV)—Environmental Characterization and Remediation (ECR) Group.

## 2.0 SCOPE

All **ECR participants** shall implement this mandatory QP when identifying, documenting, reporting, and disposition nonconformances, deficiencies, and Price-Anderson Amendments Act (PAAA) noncompliances and for verifying the implementation of corrective actions for the ENV-ECR.

**Subcontractors** performing work under the ENV-ECR quality program shall follow this QP.

## 3.0 TRAINING

3.1 **ECR participants** shall train (e.g., read and/or classroom) to and use the current version of this QP; contact the author of this QP if the text is unclear.

3.2 **ECR participants** using this QP shall document training in accordance with QP-2.2, “Personnel Training Management.”

3.3 The responsible **project leader (PL)** shall monitor the proper implementation of this procedure and ensure that the appropriate personnel complete all applicable training assignments.

3.4 **ECR participants** may request any needed assistance from the ENV-ECR Quality Integration and Improvement (QII) team in order to implement this procedure.

## 4.0 DEFINITIONS

4.1 *Apparent cause*—The most probable cause(s) that explains why the event happened, how the event can reasonably be identified, how local or facility management has the control to fix it, and what effective recommendations for corrective action(s) can be generated to remedy the problem, if necessary.

4.2 *Causal analysis*—A cause determination, based on the evaluator's judgment and experience, that establishes why the problem (nonconformance) occurred. Once data collection has been performed, one (or more) methodologies to causal analysis may include, but are not limited to, the following: events and causal factor analysis, change analysis, barrier analysis, management oversight and risk tree analysis, Kepner-Tregoe problem solving and decision-making, and root cause analysis (when required).

4.3 *Causal factor*—An event or condition that either caused the problem (nonconformance) or contributed to the unwanted result. If it were not for this event or condition, the unwanted result would not have occurred or would have been less severe.

4.4 *Condition adverse to quality*—An all-inclusive term that refers to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one which, if uncorrected, could have a serious effect on safety or operability.

4.5 *Conditional release*—Documented authorization to continue working on or to continue using a nonconforming item, sample, or product before implementing an authorized corrective action report (CAR) disposition. A conditional release may be used to direct additional work activity necessary to provide information required to develop or determine a CAR disposition.

4.6 *Corrective action*—Measure taken to rectify conditions adverse to quality, and where necessary, to preclude repetition of those conditions.

4.7 *Corrective action report*—A document used to report the corrective action(s) for nonconformances, deficiencies, and PAAA noncompliances.

4.8 *Counterfeit Item*—An item that is a copy or substitute (a copy submitted by a supplier without legal right or authority to do so) or an item whose material, performance, or characteristics are knowingly misrepresented by the supplier.

4.9 *Data admissibility determination*—The determination that data are suitable for admission to a court of law. Rule 901, "Requirement of Authentication or Identification," of the Federal Rules of Evidence defines regulatory requirements for data admissibility. In general, the admissibility of data as evidence involves the following determinations:

- The data have not been altered or contaminated (e.g., by sampling procedures).
- The test equipment was properly calibrated.
- Scientifically accepted methods were used.
- Chain of custody was maintained and identification can be made of all individuals who handled the evidentiary data.

Guidance for determining admissibility specifically for the use of accepted scientific methods may be obtained from historical forensic and pharmaceutical law cases; however, the findings of the *U.S. Supreme Court in Daubert v. Merrel Dow Pharmaceuticals, Inc.* (1993) are most often referenced. According to these findings, to be admissible in a court of law, the scientific method used to obtain the data must meet the following requirements:

- It can be (and was) tested.
- It was subjected to peer review and publication.
- The error rate associated with the approach or methodology either is known or can be estimated.
- Standards exist and can be maintained to control its operation (i.e., it is supported by well-defined procedures for use).
- It has attracted (i.e., achieved) widespread acceptance within a relevant scientific community.
- It produces data that meet all the regulatory or permit requirements as well as data quality objectives for such criteria as (but not limited to) detection limit, target list, and selectivity.

4.10 *Data quality determination*—The determination that samples were collected, analyzed, and reproduced by using known and acceptable procedures that can be verified (see Section 4.6).

4.11 *Deficiency*—A condition adverse to the quality of an activity, attribute, document, or procedure.

4.12 *Discard*—The disposition that is authorized when a nonconforming sample or item is considered unacceptable for its intended use.

4.13 *Disposition*—Actions/activities taken to resolve an identified nonconforming condition. Dispositions can include rework, repair, reject, or use as-is.

4.14 *Dispositioner*—The ENV-ECR Group participant assigned responsibility for identifying impacts to the project that may result from an identified deficiency or nonconformance, performing root cause analysis, and identifying appropriate corrective action for a deficiency and/or nonconformance.

4.15 *Initiator*—The person who initiates a CAR.

4.16 *Item*—An all-inclusive term used to represent any of the following: assembly, component, environmental sample, equipment, material, module, part, structure, subassembly, subsystem, system, or unit.

4.17 *Nonconformance*—A deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

4.18 *Price-Anderson Amendments Act of 1988*—Federal legislation that provides the legal framework for the regulation and enforcement of nuclear safety standards. The history of the PAAA is rooted in the Atomic Energy Act (AEA) of 1954. The AEA, as amended, established provisions for the indemnification and limitation of public liability arising from nuclear incidents. In 1988, the PAAA was signed into law to renew the authority of the U.S. Department of Energy (DOE) to indemnify contractors.

DOE's process and regulatory authority for its enforcement program are embodied in regulation 10 CFR Part 820, supplemented by the Enforcement Policy (Appendix A to 10 CFR Part 820) and by guidance documents. DOE may pursue a path that includes any of the following, based on the facts and significance of a PAAA violation:

1. Monitor the contractor's corrective actions with no further action
2. Issue an enforcement letter
3. Issue a notice of violation with no civil penalty
4. Issue a notice of violation with civil penalty
5. Provide a Consent Order
6. Provide a Compliance Order
7. Refer the matter to the Department of Justice for criminal prosecution

Decisions on severity level, the type of enforcement action, and amount of any civil penalty depend on safety significance, the contractor's initiative in identifying and reporting the problem, and timeliness and effectiveness of the corrective actions. When the contractor appropriately addresses these elements, the DOE can waive all or part of the civil penalties and, in some cases, entirely refrain from actions. The PAAA statute provides exemption of certain DOE not-for-profit entities for any liability for civil penalties. However, DOE may impose notices of violation for these contractors.

4.19 *Reject*—An item suspected or determined to be out of specification.

4.20 *Repair*—The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though the item still does not conform to the original requirement.

4.21 *Rework*—The process by which an item is restored to its original specifications by completion or correction.

4.22 *Scrap*—A disposition status rendering the item unsuitable for use.

4.23 *Suspect/counterfeit items*—An item whose documentation, appearance, performance, material, or other characteristics are knowingly misrepresented by the supplier.

4.24 *Suspect Item*—An item that indicates upon visual inspection, testing, or other information that it may not conform to established government or industry-accepted specifications or national consensus standards.

4.25 *Use as-is*—A disposition permitted for a nonconforming item when it has been established that the item is satisfactory for its intended use.

## 5.0 RESPONSIBLE PERSONNEL

The following personnel are responsible for activities identified in this procedure:

- Appropriate management
- Dispositioner
- Health, Safety, and Radiation (HSR) protection representative
- Initiator
- Participants
- Project leader
- Quality program project leader (QPPL)
- Quality specialist (QS)
- ENV Division PAAA coordinator
- ENV-ECR Group PAAA coordinator
- ECR participants
- Subcontractors
- User

## 6.0 PROCEDURE

6.1 Discover and Report a Nonconformance

**Note:** Anyone working on a project with the ENV-ECR Group may initiate a CAR.

6.1.1 Upon discovering a nonconformance, the **initiator** shall contact a QS to help initiate a CAR (Attachment C).

**Note:** Attachment D provides instructions for completing the CAR.

6.1.2 The **QS** shall enter the CAR into the CAR tracking database.

6.1.3 The **QPPL** shall maintain the original and copies of the CAR files until the CAR is closed.

6.1.4 If a CAR addresses a suspect/counterfeit item, the **QPPL** shall report the discovery in accordance with Laboratory Implementation Support Document (ISD)-330-09, “Suspect/Counterfeit Items.”

6.1.5 If appropriate, the **initiator** and/or the **QS** shall apply a hold tag to prevent further processing, installation, or inadvertent use of the item. Hold tags may be obtained from the QPPL or QS.

6.1.6 If the CAR addresses a serious condition adverse to quality, the **initiator** and/or the **QS** shall initiate a stop-work report in accordance with ENV-ECR QP-10.3, “Stop Work and Restart.”

6.1.7 If a potential PAAA noncompliance is identified, the **QPPL** shall submit a CAR to the ENV-ECR Group PAAA coordinator for review.

6.1.8 A causal analysis will be performed for each CAR to document the most probable cause(s) that explains and identifies why the event happened. The level of the analysis will be determined based on the severity of the issue. Guidance on performing a causal analysis may be found in DOE Standard, DOE-NE-STD-1004-92, “Root Cause Analysis” and the Laboratory Implementation Guidance Document (LIG)-307-01-05, “Issues Management Guidance Handbook.”

6.2 Perform a PAAA Determination

6.2.1 If the **QPPL** reviews the requirements for PAAA nonconformances, the **QS** shall send the CAR form to the **ENV-ECR Group PAAA coordinator** to review if a PAAA nonconformance exists.

6.2.2 The **ENV-ECR Group PAAA coordinator** shall review the CAR to determine if a PAAA noncompliance exists and will complete Section III of the CAR.

6.2.3 If a noncompliance exists, the **ENV-ECR Group PAAA coordinator** shall consult with the ENV Division PAAA coordinator for review and noncompliance evaluation.

6.2.4 If the noncompliance is determined to be a potential PAAA violation, the **ENV-ECR Group PAAA coordinator** shall implement the appropriate PAAA requirements as directed by the ENV Division PAAA coordinator and inform the QPPL of this action.

6.3 Perform an HSR Review

6.3.1 If it is determined that the CAR addresses HSR considerations, the **QPPL** shall forward the report to the HSR representative for evaluation.

6.3.2 The **HSR representative** shall evaluate the report to determine if the stated disposition adequately addresses HSR concerns.

6.3.3 Upon concurrence, the **HSR representative** shall sign and date Section III, Item 22, of the CAR form and forward it to the QPPL.

6.4 Implement a CAR Disposition

The assigned **dispositioner** shall complete Section II of the CAR by entering the appropriate information in Items 13 through 18 (refer to Attachment D for specific guidance).

6.5 Log and Number a CAR

6.5.1 The QPPL shall maintain a database for tracking CAR progress and status.

6.5.2 The QPPL and the assigned QS shall use the ECR CAR database to record, at a minimum, the following information:

- Whether or not the CAR is open or closed
- Document the (CAR) number
- CAR issue date
- Name of the CAR initiator
- Nonconformance/deficiency subject
- Name of the dispositioner
- Response due date
- Response received date
- Corrective action verification date
- Remarks

6.6 Initiate a CAR Closeout

6.6.1 When Sections I, II, III, and IV of the CAR are completed, the QPPL shall assign a QS to verify the effectiveness of the implemented corrective action in accordance with Attachment C (i.e., ensure that implementation both resolves and precludes any recurrence of the nonconformance or deficiency).

6.6.2 If the noted corrective action properly addresses and/or resolves the nonconformance or deficiency after the QS completes the verification, the QS shall forward the report to the QPPL for review and concurrence. The QPPL shall update the CAR report log in accordance with Attachment C.

6.6.3 If applicable, the initiator and/or QS shall ensure and document the removal of hold tags.

6.6.4 After the CAR closure, the QPPL shall ensure the entry of all appropriate CAR data into the CAR tracking log.

6.7 Report Overdue Corrective Action

6.7.1 If a CAR remains open beyond the period agreed upon by the QPPL, dispositioner, and the responsible PL, the QPPL shall assign a QS to follow up and resolve the open CAR.

6.7.2 If properly implementing corrective action and closing out the CAR require additional time, the QPPL shall assign a new closure date.

6.7.3 The QPPL shall implement this action by initiating and submitting a memorandum to the dispositioner and attaching a copy of the memorandum to the CAR on file.

6.7.4 If the QPPL finds that no action and/or no effort was made to respond to a submitted CAR and/or implements the identified corrective action, the QPPL shall forward the CAR to the ENV-ECR Group management.

6.7.5 The QPPL shall, if warranted, initiate a stop-work/restart report.

6.7.6 If the CAR addresses a nonconformance, the QPPL shall also submit the CAR and stop-work/restart report (if applicable) in accordance with QP-10.3 to the ENV Division PAAA coordinator for review and additional processing.

6.8 Revise or Modify CARs

The initiator, QPPL, and/or QS may revise or modify a previously issued CAR, if warranted.

6.8.1 The justification for revision will be documented in the block or blocks to be revised.

6.8.2 Appropriate signature(s) must be reattained for the block or blocks revised.

6.8.3 A revision number to the CAR shall be noted in the upper-right corner of the CAR.

6.9 Resolve a Dispute Regarding a CAR

**Appropriate management** shall handle disputes that arise during implementation of this procedure. If not resolved, the matter is elevated to progressively higher levels of management.

**Note:** Forward any created documentation to the QPPL as relevant correspondence to be included with the CAR as a record.

6.10 Develop a Trend Report

The **QPPL** shall use the accumulated CAR data to develop a trend report and submit the report to management quarterly or as requested.

**Note:** The report documents both the status of open and closed CARs and data that applies to the identified areas of concern.

## 7.0 LESSONS LEARNED

7.1 Before performing work described in this QP, **ECR participants** should go to the Department of Energy Lessons Learned Information Services home page, located at http://www.eh.doe.gov/ll/ll.html, and/or to the LANL Lessons Learned Resources web page, located at http://int.lanl.gov/projects/lessons_learned/, and search for applicable lessons.

7.2 During work performance and/or after the completion of work activities, **ECR participants**, as appropriate, shall identify, document, and submit lessons learned in accordance with the LANL Lessons Learned System located at http://int.lanl.gov/projects/lessons_learned/.

## 8.0 RECORDS

The **QPPL** shall submit the following records to the Records Processing Facility, in accordance with QP-4.4:

- Completed CARs
- Electronic copy of the CAR and associated documents
- Completed ENV-ECR document signature form
- All documentation associated with the CAR (e.g., data, records, inspection reports) that support or provide evidence condition resolution and final acceptance

## 9.0 REFERENCES

9.1 To implement this QP properly, **ECR participants** should become familiar with the contents of the following documents, each of which is available at http://erinternal.lanl.gov/procedures.shtml:

- ENV-ECR, "Quality Management Plan"
- QP-2.2, "Personnel Training Management"
- QP-4.4, "Records Transmittal to the Records Processing Facility"
- QP-10.3, "Stop Work and Restart"
- Nuclear Quality Assurance-1 2000, "Quality Assurance Requirements for Nuclear Facility Applications"
- DOE Order 414,1B, "Quality Assurance"
- Inspection Procedure 300-SD 3.2, "Quality Assurance Program (LANL)"
- ISD 330-6.0, "Nonconformance Reporting"

9.2 **ECR participants** using this QP should also become familiar with the contents of the following documents available at the website addresses provided:

- LANL Laboratory Implementation Requirement 401-10-01, "Stop Work and Restart" (available at http://int.lanl.gov/orgs/s/s-1/documents/SAFETY/LIRS/lir4011001.pdf)
- LANL, "Integrated Safety Management Description Document," LA-UR-98-2837 (available at http://int.lanl.gov/orgs/s/s-1/documents/SAFETY/LAUR/laur982837.pdf)
- PAAA (available at http://www.eh.doe.gov/enforce/)
- DOE Standard No. DOE-NE-STD-1004-92, "Root Cause Analysis Guidance Document" (available at http://tis.eh.doe.gov/techstds/standard/nst1004/nst1004.pdf)
- LANL Operational Support Tool, OST 402-130-01, "Laboratory Occurrence Reporting Requirement/Guidance" (available at http://policies.lanl.gov/pods/policies.nsf/MainFrameset?ReadForm&DocNum=OST402-130-01&FileName=ost40213001.pdf)
- DOE, DOE Office of Enforcement and Investigation (EH-10) Operational Procedure (supersedes DOE-HDBK-1089-95) "Identifying, Reporting, and Tracking Nuclear Safety Noncompliances under Price-Anderson Amendments Act of 1988," (available at http://tis.eh.doe.gov/enforce/handbks/hndbkr4g.pdf)

- DOE Order 231.1A, “Environment, Safety, and Health Reporting” (cancels DOE O 232.1A) (available at http://tis.eh.doe.gov/feosh/resource/440-1a.htm)
- U.S. Department of Justice, Rules of Evidence, Article IX, Rule 901, “Requirement of Authentication or Identification” (available at http://www.house.gov/judiciary/Evid2002.pdf)
- DOE, DOE Standard, DOE-NE-STD-1004-92, “Root Cause Analysis”
- LANL, LIG-307-01-05, “Issues Management Guidance Handbook.”

## 10.0 ATTACHMENTS

The responsible **ECR participant** may locate all forms associated with this procedure at http://erinternal.lanl.gov/Quality/user/forms.asp.

Attachment A: List of Acronyms and Abbreviations, 1 page

Attachment B: Evaluation of Nonconformance, Deficiency, Noncompliance, and Stop Work Conditions for Corrective Action, 2 pages

Attachment C: Corrective Action Report form, 2 pages

Attachment D: Corrective Action Report Completion Instructions, 4 pages

Using a CRYPTOCard, click here to record "self-study" training to this procedure.

If you do not possess a CRYPTOCard or encounter problems, contact the ENV-ECR training specialist.

## Attachment A: List of Acronyms and Abbreviations

| | |
|---|---|
| AEA | Atomic Energy Act |
| CAR | corrective action report |
| DOE | U.S. Department of Energy |
| ECR | Environmental Characterization and Remediation Group |
| ENV | Environmental Stewardship Division |
| HSR | Health, Safety, and Radiation |
| ISD | implementation support document |
| LANL | Los Alamos National Laboratory |
| LIG | Laboratory implementation guideline |
| PAAA | Price-Anderson Amendments Act |
| PL | project leader |
| QII | Quality Integration and Improvement |
| QMP | quality management plan |
| QP | quality procedure |
| QPPL | quality program project leader |
| QS | quality specialist |

## Attachment B: Evaluation of Nonconformance, Deficiency, Noncompliance, and Stop-Work Conditions for Corrective Action

**Criteria for Evaluation**

The following criteria are used to evaluate a condition or item to determine if it presents a nonconformance or deficiency and, if so, if the nonconformance or deficiency may involve Price-Anderson Amendments Act (PAAA) noncompliance. Items or conditions identified as nonconformances or deficiencies must be reported using the Corrective Action Report (CAR) form (Attachment C).

Nonconformance

A nonconformance is a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate. A nonconformance demonstrates the following traits:

- Significant failure or breakdown in the implementation of quality program requirements
- Significant discrepancy between an approved design and the design's implementation
- Counterfeiting or false representation of an item's quality and characteristics
- Damage, such as that caused by improper construction, shipping, handling, or storage that results in extensive evaluation, redesign, or repair to meet accepted or required quality and safety criteria
- Compromise of or in items or activities important to safety or waste isolation that prevents mitigation of hazards to the safety and health of workers and/or the public

Deficiency

A deficiency is a condition adverse to quality in an activity, attribute, document, data, or procedure that renders the quality of the activity unacceptable or indeterminate. Examples of deficiencies are

- noncompliance to a procedure, plan, or program requirement;
- use of and/or reference to superseded or outdated documents (e.g., standard operating procedures or U.S. Department of Energy orders); and
- use of or reliance upon analytical data of indeterminate quality.

## Attachment B: (continued)

Noncompliance

A noncompliance is a nonconformance or deficiency that results in the failure to comply with a nuclear quality or safety requirement, specifically regarding the regulations that the PAAA established.

Stop-Work Condition

A stop-work condition exists when continuing work would cause one or more of the following:

- Irreparable compromise to the quality of scientific investigation results
- Continued use of an item that does not function as intended because of a nonconformance in processing, installation, modification, or operation
- Continued use of a suspect/counterfeit item
- Significant hazard to the health or safety of workers and/or the public
- Significant breakdown or failure in the implementation of quality program requirements
- Compromise in the quality of items or activities important to safety or waste isolation

# Attachment C: Corrective Action Report (CAR)

(Use additional pages as necessary; refer to instructions in Attachment C.) No. of pages:____

**Section I. Initiation** (Initiator completes.)

| | |
|---|---|
| 1. Subject: | 1. CAR No. ER200_-____ (Document Catalog Number)<br>Rev. _____<br>☐ Item ☐ Documentation ☐ Process/Procedure |

3. Initiator: _____
(Print name, then sign) (Date)

| | |
|---|---|
| 4. Related CAR number(s): | 5. Controlling documents (e.g., field implementation plan, memorandum of understanding, quality management plan, quality procedure, standard operating procedure, statement of work): |

6. Requirement:

7. Describe the nonconforming/deficient condition:

| | | |
|---|---|---|
| 8. Stop work?<br>☐ No ☐ Yes | 9. Health, Safety and Radiation (HSR) issue?<br>☐ No ☐ Yes | 10. Hold tag applied? ☐ No ☐ Yes ☐ N/A |

11. Disposition assigned to: _____
(Print name)

12. Responsible manager: _____
(Print name, then sign) (Date)

**Section II. Disposition** (Dispositioner completes items and submits form to the QPPL within 5 working days)

13. ☐ Rework ☐ Repair ☐ Use as-is ☐ Limited use ☐ Discard ☐ Reject/scrap ☐ Suspect/counterfeit

14. Immediate corrective action: Projected completion date:

15. Apparent cause/ causal analysis:

16. Project/item impact:

17. Corrective action to prevent recurrence: Projected completion date:

18. Disposition submitted by: _____
(Print name then sign.) (Date)

**Section III. Potential PAAA Noncompliance Evaluation** ( Environmental Stewardship (ENV) Division–Environmental Characterization and Remediation Group/Price-Anderson Amendments Act (PAAA) coordinator completes)

19. PAAA issue? ☐ No ☐ Yes. If "Yes," enter a statement addressing the evaluation and Los Alamos National Laboratory PAAA determination:

20. PAAA coordinator : _____
(Print name then sign) (Date)

21. Submitted to the ENV-ECR Group PAAA coordinator for review? ☐ No ☐ Yes Date: _____

**Section IV. Disposition Approvals** (HSR representative and quality program project leader( QPPL) complete)

22. HSR reviewer: _____
(Print name. then sign) (Date)

23. QPPL reviewer: _____
(Print name. then sign) (Date)

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## Attachment C: Corrective Action Report (continued)

(Use additional pages as necessary; refer to instructions in Attachment C.) No. of pages:____

Section V. Verification of Corrective Action Activities (Quality specialist and QPPL complete)

24. Description of method and results of verification (e.g., assessment, inspection, surveillance)

25. Further investigation required? ☐ No ☐ Yes If "Yes," explain:

26. Verified by: Quality specialist _____

(Print name. then sign) (Date)

27. Concurred by: QPPL _____

(Print name. then sign) (Date)

## Attachment D: Corrective Action Report Completion Instructions

The numbered steps represent the numbered items on the Corrective Action Report (CAR) form. Complete only the applicable information. Mark items that do not apply as "n/a."

**Note**: Use a continuation page or reference attachments if additional space is required.

**Section I. Initiation**

The **initiator** completes Section I.

1. Enter information that identifies the subject of the CAR.
2. Enter the report number. Check either "Nonconformance" or "Deficiency" (refer to Quality Procedure (QP)-4.9, "Document Development and Approval Process," to obtain a document catalog number and to QP-3.4, Sections 4.5 and 4.13, to determine the type of report being submitted).
3. Print your name (initiator only), sign, and date.
4. Enter the number of the report that resulted in identifying the nonconformance or deficiency (e.g., assessment report, surveillance report, nonconformance/deficiency report, inspection report). Enter n/a if no related report exists.
5. Enter title, revision number, effective date, and document catalog number, if applicable, for the document that controls the nonconforming or deficient item.
6. State, in concise, narrative form, the nonconforming/deficient condition found; include specific references (i.e., by paragraph and/or section number) to the controlling document and revision numbers.
7. Describe, in concise, narrative form, the nonconforming/deficient condition found; include references to the results of any preliminary investigations.
8. Check "No" if there is not a stop-work condition; "Yes" if there is a stop-work condition.
9. Check "No" if there is no health, safety, or radiation (HSR) protection issue; "Yes" if there is an HSR protection issue.
10. Check "No" if a hold tag has not been applied; "Yes" if a hold tag has been applied, and n/a if this action is not applicable.
11. Enter the name of the Environmental Stewardship-Environmental Characterization and Remediation (ENV-ECR) program participant assigned to disposition the report.
12. Have the responsible manager (e.g., ENV-ECR Group leader, subcontractor manager) print his or her name, sign, and date.

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## Attachment D: (continued)

**Section II. Disposition**

The **dispositioner** completes Section II.

13. Check the item that best reflects the process that will be followed to address the nonconformance: rework, repair, use as-is, limited use, discard, reject/scrap, or suspect/counterfeit.

14. Enter a statement that identifies what corrective actions were taken to immediately correct and/or control the nonconformance or deficiency. Enter the projected completion date for the corrective action described.

**Note:** The statement of corrective action for the disposition of nonconforming items may include documentation of applied procedures, technical justification, and/or a statement addressing conditional release. Guidance for determining the applicability of these items to the corrective action statement follows.

**Applied Procedures**

For nonconforming items for which corrective action includes a designation of repair, **use as-is, limited use**, or **suspect/counterfeit**, the corrective action statement should demonstrate, in concise, narrative form, the procedures applied to the disposition. These procedures may include

QP-3.4, Sections 6.1.4 and 6.1.5—for removing, tagging, controlling, and reporting suspect/counterfeit items to prevent continued use; and

QP-3.4, Section 6.2—for reporting and to disposition potential PAAA noncompliance.

**Technical Justification**

For nonconforming items for which corrective action includes a designation of repair or **use as-is**, the corrective action statement should include technical justification. The technical justification may include statements addressing

- the item's acceptability and how the item will continue to be subject to design controls (e.g., change document or other design revision),
- any action required to change the specifying document(s) or records to reflect acceptance of the nonconformance, and/or
- any requirement to reexamine repaired or reworked items and products in accordance with the original criteria or the criteria as revised to address the nonconformance.

## Attachment D: (continued)

**Conditional Release**

Corrective action for nonconforming items dispositioned as **limited use**, **repair**, or **use as-is** should include documented justification for the item's conditional release. The justification, a statement of applicable limitations and appropriate approvals, may be included as an attachment to the CAR form. When establishing conditional release, the dispositioner should consider whether

- the nonconforming item can be removed without unacceptable damage to its associated product(s);
- access to the item is necessary for any required inspections, tests, and/or continued but limited use; or whether
- tracing identification should be or has been established.

**Note:** Conditional release may also be used when additional work is necessary to determine appropriate disposition for a nonconforming item.

15. Enter in narrative form the identified root cause and contributing causes for the nonconformance or deficiency. Guidance for performing a root cause analysis is available at http://tis.eh.doe.gov/techstds/standard/nst1004/nst1004.pdf.
16. Enter a descriptive statement that identifies the impact of the nonconformance or deficiency upon the ENV-ECR Group and/or the nonconforming item itself.
17. Enter in narrative form the corrective action(s) taken to prevent recurrence of the nonconformance or deficiency and the projected date by which the action(s) will be completed.

**Note:** The results of the root cause analysis should be used to determine the appropriate corrective action to prevent recurrence.

18. Print your name (dispositioner only), sign, date, and submit the form to the quality program project leader (QPPL) for further processing.

Section III. Potential Price-Anderson Amendments Act (PAAA) Noncompliance Evaluation

The ENV-ECR Group PAAA coordinator completes Section III.

19. Check "No" if the nonconformance or deficiency is not a potential PAAA noncompliance. If the nonconformance or deficiency is a potential PAAA noncompliance, check "Yes" and enter a statement addressing the PAAA evaluation and determination.
20. Print your name (ENV-ECR Group PAAA coordinator only) sign, and date.
21. Check "No" if the CAR will not be submitted to the ENV-ECR Group PAAA coordinator for review and date. Check "Yes" if the CAR has been submitted to the ENV-ECR Group PAAA coordinator and enter the date of submission.

## Attachment D: (continued)

**Section IV. Disposition Approvals**

The HSR representative and the QPPL complete Section IV.

**Note:** Refer to Section I, Item 9, of the CAR form. If the response indicated is "No," the dispositioner enters "n/a" on the line for Item 22.

22. (HSR representative completes.) Review Section II of the CAR form. If you approve the information provided in Section II, print your name, sign, and date. If you do not approve Section II as completed, attach a statement to the CAR form describing your determination. Return the CAR form to the QPPL (refer to QP-3.4, Section 6.3).

23. (QPPL completes.) Review Section II of the CAR form and the HSR information. If you approve the CAR form as completed, print your name, sign, and date. If you do not approve the CAR form as completed, return the form to the dispositioner for further action.

**Note:** If the QPPL determines that further action is required, the dispositioner should, as directed by the QPPL, resolve the disposition to complete the closure of the CAR (see QP-3.4, Section 6.5).

**Section V. Verification of Corrective Action Activities**

The quality specialist (QS) and QPPL complete Section V.

**Note:** Verification of corrective action activities should be performed no later than 180 days after completion of the corrective action.

24. (QS completes.) Enter a narrative description of the method (e.g., assessment, surveillance, inspection, test) used to verify disposition of the nonconformance or deficiency and the results of the verification. As applicable, identify all documents reviewed (include title, number, effective date, and identification number), employees interviewed, and measuring and test equipment used.

25. (QS completes.) Check "No" if no further investigation is required. If further investigation is required, check "Yes" and explain how further investigation will be implemented.

26. (QS completes.) Print your name, sign, date, and submit the form to the QPPL for approval and signature.

27. (QPPL completes) Review Item 25. If no further investigation is required, then indicate your concurrence with the CAR by printing your name, signing, and dating the CAR. If further action is required and the CAR cannot be closed, create an entry to the CAR tracking log explaining the reasons the CAR will remain open.